Registration Decision RD2012-05

Icaridin

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Registration Decision for Icaridin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Icaridin Technical Insect Repellent, All-Family Insect Repellent Spray, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent Spray I, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent Spray II, OFF! Active Insect Repellent Clean Feel, OFF! Family Care Clean Feel Insect Repellent Towelettes and OFF! Deep Woods Pump Spray Insect Repellent Clean Feel, containing the technical grade active ingredient icaridin, as a personal insect repellent against mosquitoes and various pests as indicated on the label.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-10, *Icaridin*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for icaridin and summarizes the Agency's decision. The PMRA received no comments on PRD2011-10. This decision is consistent with the proposed registration decision stated in PRD2011-10.

For more details on the information presented in this Registration Decision, please refer to the PRD2011-10 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Icaridin?

Icaridin is the active ingredient contained in All-Family Insect Repellent Spray, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent I, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent II, OFF! Active Insect Repellent Clean Feel, OFF! Deep Woods Pump Spray Insect Repellent Clean Feel and OFF! Family Care Clean Feel Insect Repellent Towelettes. It is a personal insect repellent for application on human skin. Its mode of action is not fully understood. One hypothesis is that icaridin affects arthropod olfactory neurons, resulting in their inability to detect host attractants. Another is that the repellent evaporates from the skin into the air, forming a layer of scent that camouflages the attractants (carbon dioxide and lactate) emitted by the human host, and therefore the arthropod cannot find the host.

Health Considerations

Can Approved Uses of Icaridin Affect Human Health?

Products containing icaridin are unlikely to affect your health when used according to label directions.

Exposure to icaridin will occur through the application of insect repellent products containing this active ingredient to human skin. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when icaridin-containing insect repellent products are used according to label directions.

In laboratory animals, technical grade active ingredient icaridin was of low acute toxicity by the oral, dermal and inhalation routes of exposure. It was moderately irritating to the eyes of rabbits, and as such the hazard statement "Warning Eye Irritant" is required on the label. Icaridin was not irritating to the skin and did not cause an allergic skin reaction.

All of the end-use repellent products containing icaridin were of low acute toxicity via the oral, dermal, and inhalation routes of exposure. None of the products were irritating to the skin and none caused an allergic skin reaction. All products were moderately irritating to the eyes, and consequently the hazard statement "Warning- Eye Irritant" is required on the product labels.

Health effects in animals given repeated doses of icaridin included effects on the liver and kidney. Icaridin did not cause cancer in animals and did not damage genetic material. There was no indication that icaridin caused damage to the nervous system or immune system.

Icaridin did not have an effect on the ability to reproduce. When icaridin was given to pregnant or nursing animals, no effects on the developing fetus or juvenile animal were observed, indicating that the young do not appear to be more sensitive to icaridin than the adult animal.

The risk assessment protects against the effects of icaridin by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential and Other Non-Occupational Environments

Residential and other non-occupational bystander risks are not of concern when All-Family Insect Repellent Spray, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent Spray I and II, OFF! Active Insect Repellent Clean Feel, OFF! Deep Woods Pump Spray Insect Repellent Clean Feel, and OFF! Family Care Clean Feel Insect Repellent Towelettes are used according to label directions.

People who apply the products to themselves as well as people who have the products applied to them, come in direct contact with icaridin residues on the skin. Therefore, the domestic uses of the 10% and 20% icaridin pump spray, the 10% icaridin aerosol and the 20% icaridin towelettes as personal insect repellents are considered acceptable for adults, youth, children, toddlers and infants (>6 months).

Taking into consideration the product specific application rates, the number of applications, the protection time and the exposure duration, it was determined that the risks to these individuals are not a concern.

For bystanders, exposure was not quantified, as it is expected to be minimal in comparison to the exposure to users. Therefore, health risks to bystanders are not of concern.

Occupational Risks From Handling All-Family Insect Repellent Spray, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent Spray I and II, OFF! Active Insect Repellent Clean Feel, OFF! Deep Woods Pump Spray Insect Repellent Clean Feel, and OFF! Family Care Clean Feel Insect Repellent Towelettes

Occupational risks from handling the icaridin products were not quantified, as it is expected that workers will not use these products in greater quantities than residential users. Therefore, health risks to workers are addressed by those of residential users.

Value Considerations

What Is the Value of All-Family Insect Repellent Spray, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent I, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent II, OFF! Active Insect Repellent Clean Feel, OFF! Deep Woods Pump Spray Insect Repellent Clean Feel and OFF! Family Care Clean Feel Insect Repellent Towelettes?

These end-use products repel mosquitoes, ticks and black flies, which are important blood-feeding pest arthropods.

Sufficient efficacy data were provided to support the following uses:

- All-Family Insect Repellent Spray (containing 20% icaridin) for seven hours of protection from mosquitoes and eight hours of protection from ticks. Use of these products to provide eight hours of protection from black flies was conditionally supported.

- Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent I and Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent II (containing 10% icaridin) for five hours of protection from mosquitoes. Use of these products to provide seven hours of protection from ticks was conditionally supported.

- OFF! Active Insect Repellent Clean Feel (containing 10% icaridin) for five hours of protection from mosquitoes.

- OFF! Deep Woods Pump Spray Insect Repellent Clean Feel and OFF! Family Care Clean Feel Insect Repellent Towelettes (containing 20% icaridin) for seven hours of protection from mosquitoes and eight hours of protection from ticks.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of All-Family Insect Repellent Spray, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent Spray I, Avon Skin-So-Soft SSS Bug Guard Plus Icaridin Insect Repellent Spray II, OFF! Active Insect Repellent Clean Feel, OFF! Family Care Clean Feel Insect Repellent Towelettes and OFF! Deep Woods Pump Spray Insect Repellent Clean Feel, to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

A risk assessment was not performed for infants under six months of age since it is assumed that non-chemical measures can be utilized to protect this population from biting pressures. Therefore, all products carry the statement: "Do not use on infants under 6 months of age".

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-10, *Icaridin)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/indexeng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*